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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,320

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EXAMINER

MONTANARI, DAVID A

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,320	Applicant(s) KINGSMAN ET AL.	
	Examiner DAVID MONTANARI	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 18-24, 31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 18-24, 31 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants arguments and amendments filed on 2/15/2008 have been entered.
2. Claims 13 and 24 are amended.
3. Claims 1-12, 14-17, 25-30, 32, 33 and 35-40 are cancelled.
4. Claims 13, 18-24, 31 and 34 are examined in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 18-24, 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Naldini et al, 1996, Science, Vol. 272, pgs. 263-267) in view of Schnell et al. (2000, Human Gene Therapy, Vol. 11, pgs. 439-447) and Gregoire et al. (1998, Physiological Rev., Vol. 78, pgs. 783-809).

Naldini et al. teach that a limitation of retroviral vectors is their inability to transduce non-dividing cells and that an "optimal gene transfer system would include a retroviral vector based upon a virus, such as HIV or other lentiviruses, that can integrate into the genome of nonproliferating cells" (pg. 263, col. 1, lines 12-17). With regard to claims 20 and 23 Naldini teaches that "The ability of HIV-based viral vectors to deliver genes in vivo into nondividing cells could increase the applicability of retroviral vectors in human gene therapy" (pg. 263, Abstract, last three lines). With regard to claims 13, 18, 19, 21, 22, 24, 31 and 34, Naldini

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teaches that an HIV-based vector was generated with the CMV promoter (pg. 263, col. 1, parag. 2), pseudotyped with VSV-G to broaden the tropism (pg. 263, col. 2, lines 11-16), comprised either beta-galactosidase or luciferase (pg. 263, col. 3 parag. 1, last 5 lines) and used to transduce 208F rat fibroblasts (pg. 264 col. 1 lines 1-2). Naldini et al. do not teach a method of transducing adipose tissue.

However, at the time of filing the ordinary artisan would have found it routine to transduce post-mitotic/nondividing cells with a lentiviral vector. At the time of filing and addressing claim 21, Schnell et al. teaches that lentiviruses do not require cell division for integration into the host genome and that lentiviral vectors can therefore expand the spectrum of target cells susceptible to retroviral gene transfer (pg. 439, Abstract, lines 1-2). Regarding claims 13 and 24, Schnell teaches that VSV-G was used expand the tropism of their lentiviral construct and that pseudotyping with VSV-G was determined to be most efficient for generating viral titres (pg. 442, col. 1 parag. 1). Gregoire et al. teach that adipocytes are terminally differentiated cells that no longer divide after acquiring sensitivity to insulin (pg. 790, col. 1, parag. 2 and Abstract, lines 3-5).

Thus the ordinary artisan would have been motivated at the time of filing to transduce nondividing cells, such as adipocytes in adipose tissue, with a lentiviral vector pseudotyped with VSV-G given the combined teachings and motivation of Naldini, Schnell and Gregoire. Gregoire provides motivation to the ordinary artisan in teaching that adipocytes are terminally differentiated cells which no longer divide. Naldini provides additional motivation to the ordinary artisan in teaching that the delivery of genes to nondividing cells is therapeutically important and achievable using based upon their results. Given this broad teaching, the ordinary

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artisan would be motivated to provide POI, NOI, including ones that encode therapeutic proteins and NOI's that block or inhibit the expression of a gene in a adipose cell. Schnell provides additional motivation to the ordinary artisan teaching that lentiviruses are suitable vectors for delivering genes to nondividing cells and that using VSV-G expands tropism as well as improve virus titres. Given the teachings discussed above the cited art provides the requisite teachings and motivations to make and use the claimed invention. Further the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.
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/Peter Paras, Jr./
Peter Paras, Jr.
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